IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellant:	Jay A. Goldstein, Michael Rothman, and Whe-Yong Lo		
Serial No.:	10/691,928	Art Unit:	1616
Filed:	October 23, 2003	Examiner:	David Paul Stitzel
For:	*ANTIFUNGAL FORMULATIONS*		

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF

Sir:

This is an appeal from the rejections of the claims in the Office Action mailed on March 23, 2006, and maintained in the Advisory Action mailed July 27, 2006. A Notice of Appeal was filed June 23, 2006. A Petition for an Extension of Time for one month, up to and including September 23, 2006, accompanies this Appeal Brief. The Commissioner is hereby authorized to charge the fee for filing of this Appeal Brief and Petition for Extension of Time to Deposit Account No. 50-3129.

(1) REAL PARTY IN INTEREST

The real party in interest of this application is the assignee, G&R Pharmaceuticals, LLC, and the licensee, BTG International Inc.

(2) RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences known to appellant, the undersigned, or appellant's assignee which directly affects, which would be directly affected by, or which would have a bearing on the Board's decision in this appeal.

(3) STATUS OF CLAIMS

Claims 1-17 are pending and on appeal. The text of each claim on appeal, as pending, is set forth in an Appendix to this Appeal Brief.

(4) STATUS OF AMENDMENTS

The claims were last amended in the Amendment filed December 27, 2005. An amendment after final rejection filed on June 23, 2006 was not entered, as indicated in the Advisory Action mailed July 27, 2006. An appendix sets forth the claims on appeal.

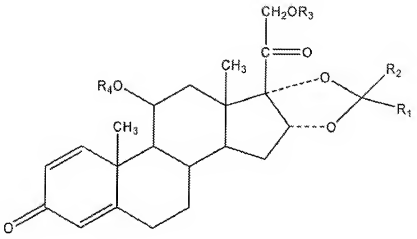
(5) SUMMARY OF CLAIMED SUBJECT MATTER

Claim 1 defines a topical formulation comprising:

a) a therapeutically effective amount of an antifungal compound for treating a fungal disease or a pharmaceutically acceptable salt thereof; and

b) a therapeutically effective amount of a low to low-medium potency steroidal anti-inflammatory causing minimal skin atrophy, striae and hypopigmentation, in a concentration between 0.01 wt% and 5.0 wt%, and having a higher potency than 1 wt% hydrocortisone. (support is found at page 2, lines 7-10; page 3, lines 19-21; page 5, lines 13-15; page 4, lines 15-16)

Claim 2 defines the antifungal composition of claim 1 wherein the steroidal anti-inflammatory has the following structure:



wherein R_1, R_2, R_3, and R_4 taken independently can be H, C1-C10 alkyl, C1-C10 alkenyl, C3-C10 cycloalkyl, and phenyl groups; R_1 and R_2 taken together can be C3-C10 cycloalkyl; and R_3 and R_4 taken independently can be H, C1-C10 alkyl, C1-C10 alkenyl, C3-C10 cycloalkyl, phenyl, C7-C10 phenylalkyl, carboxylate, sulfonyl, phosphoryl, and phosphonyl groups. Claim 3 is a smaller group of steroidal antiinflammatories, wherein R_1, R_2, R_3, and R_4 groups are independently H, CH_3, ethyl, propyl, phenyl, and phenylmethyl groups. (page 4, lines 15-25).

Claim4 is drawn to s specific combination, wherein the steroidal anti-inflammatory is desonide and the antifungal compound is clotrimazole.(page 3, lines 17-19) Claims 5 and 6 are drawn to preferred concentrations of these agents, claim 5 where the composition contains 0.01

wt % to 5.0% wt % desonide and claim 6 where the composition contains 0.1 wt % to 5 wt % clotrimazole. (original claims)

Claim 7 defines specific steroidal antiinflammatories wherein the steroidal anti-inflammatory is selected from the group consisting of Fluocinolone acetonide, Hydrocortisone valerate, Hydrocortisone butyrate, Alclometasone dipropionate, Desonide, and hydrocortisone probutate. (page 5, lines 7-12)

Claim 8 define the antifungal as selected from the group consisting of polyene type antifungal agents and azole type antifungal agents. (page 4, lines 1-5) Claim 9 defines the antifungal as selected from the group consisting of Amphoterican B, Nystatin, Flucytosin, Natamycin, Ketoconazole, Econoazole, Miconazole, Itraconazole, Fluconazole, Econazole, Clotrimazole, Griseofulvin, Oxiconazole, Terconazole, Tioconazole, Clotrimazole, Silver Sulfadiazine, Ciclopirox olamine, and Terbinafine. (page 4, lines 5-13)

Claim 10 defines the composition formulated as a cream, ointment, gel, lotion, foam, powder, aerosol, spray, shampoo, or liquid solution. (page 2, lines 22-24) Claim 11 defines this composition as having a pH of about 3.5 to about 7.0 further comprising: at least one solvent, at least one emollient, at least one humectant, at least one preservative, and at least one emulsifier; and optionally including an acid, base, or buffering agent to adjust the pH. (page 4, lines 1-3) Claim 12 defines this composition wherein the solvent is selected from the group consisting of propylene glycol, butylene glycol, hexylene glycol, polyethylene glycols, polypropylene glycols, and polyurethane compounds; the emollient is selected from the group consisting of white

petrolatum, mineral oil, propylene glycol dicaprylate, lower fatty acid esters and lower alkyl ethers of propylene glycol, cetyl alcohol, cetostearyl alcohol, stearyl alcohol, stearic acid, cetyl esters wax, spermaceti wax, and white wax; the humectant is selected from the group consisting of glycerin and sorbitol; and the emulsifier is selected from the group consisting of glyceryl monostearate, glyceryl monoleate, stearic acid, polyoxyethylene cetyl ether, polyoxyethylene cetostearyl ether, polyoxyethylene stearyl ether, and polyethylene glycol stearate; wherein the optional acid is selected from the group consisting of hydrochloric acid and phosphoric acid, the optional base is chosen from diethanolamine, triethanolamine, and sodium hydroxide, the optional buffering agent is chosen from monobasic sodium phosphate and dibasic sodium phosphate, and the preservative is chosen from benzyl alcohol, sodium benzoate and parabens. (page 6) Claim 13.defines the composition of claim 1 wherein the antifungal is in an amount effective to treat fungal disease selected from the group consisting of tinea pedis, tinea capitis, tinea corporis, tinea versicolor, scalp disorders, tinea cruris, and candidiasis. (page 8, lines 11-13)

Claim 14 is drawn to a method of treating a fungal disease comprising administering to a subject in need of treatment the composition of any of claim 1-13 or 17, with a thin application of the composition two times per day to the affected areas. (page 3, lines 16-19; original claim 14) Claim 15 defines the method wherein the subject is a child of under 10 years old. (original claim 15). Claim16 recites the method of claim 14 wherein the fungal disease is selected from the group consisting of tinea pedis, tinea capitis, tinea corporis, tinea versicolor, scalp disorders,

tinea cruris, and candidiasis. (page 3, lines 8-16; original claim 16). Claim 17 defines the composition of claim 1 wherein the steroidal antiinflammatory is not halogenated (page 2, lines 7-10; page 3, lines 19-21).

(6) GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The issues presented on appeal are:

(1) whether claim 1 complies with the written description requirement required by 35 U.S.C. § 112, first paragraph.

(2) whether claims 1-10 and 13-17 are novel as required by 35 U.S.C. § 102(a) over U.S. Patent No. 6,444,647 to Robinson.

(3) whether claims 1-5, 7-13, and 17are novel as required by 35 U.S.C. § 102(b) over U.S. Patent No. 6,075,056 to Quigley.

(4) whether claims 1-9, 13, 14, 16 and 17 are novel as required by 35 U.S.C. § 102(b) over U.S. Patent No. 5,686,089 to Mitra.

(5) whether claims 1-10 and 17 are novel as required by 35 U.S.C. § 102(b) over U.S. Patent No. 5,219,877 to Shah.

(6) whether claim 15 is non-obvious as required by 35 U.S.C. § 103 over U.S. Patent No. 5,686,089 to Mitra.

(7) ARGUMENT

The claimed compositions relate to a combination of (1) low to mid-low potency steroidal anti-inflammatory and (2) an anti-fungal.

Dr. Goldstein has been a practicing dermatologist for many years. In the course of his treatment of patients, he has observed that many mid and high potency steroids cause serious side effects, including thinning of the skin, hypopigmentation, and striae distensae, which may be as significant of a problem as the presenting condition since fungal conditions take up to four weeks to respond to treatment. During this extended period of treatment, the patient have to put up with irritation, redness and itching. Therefore there is a need for a composition that is both effective but safe, with minimal side effects.

Based on his extensive clinical experience, Dr. Goldstein has discovered that low and low-mid potency steroidal antiinflammatories can be combined with an antifungal to provide a safe and effective treatment with minimal side effects. He presented photos of one case study wherein the patient had presented with scaly red and inflamed, raised areas of skin infected with inflammatory tinea. This patient had previously been treated with a variety of medications, none of which were effective. Dr. Goldstein treated the patient with a topical cream containing 0.05% desonide and 1% clotrimazole. Within a few days, the redness and swelling had disappeared, leaving skin looking almost normal in the photographs.

The data presented at the interview demonstrated the unexpected efficacy and lack of side effects of one non-halogenated steroidal antiinflammatory, desonide, in combination with an

antifungal. Additional data showing the same unexpected efficacy and lack of side effects for other members of the claimed class of low to low-mid potency steroidal antiinflammatories is submitted in the Declaration under 37 C.F.R. § 1.132 by Dr. Goldstein (Appendix). Members of the claimed class that have been shown to produce results comparable to a topical cream containing 0.05% desonide and 1% clotrimazole are:

Clotrimazole 1% cream with alclometasone dipropionate 0.05% cream applied twice daily:

Oxiconazole cream 1% with Hydrocortisone cream 2½% applied twice daily;

Econazole cream 1% with fluocinalone acetonide cream 0.01% applied twice daily; and

Econazole cream 1% with alclometasone dipropionate 0.05%, applied twice daily.

The claimed combination is counter-intuitive.

(i) Rejection under 35 U.S.C. § 112, first paragraph

Claim 1 complies with the written description requirement required by 35 U.S.C. § 112, first paragraph.

a. The Legal Standard for Written Description

Both the written description and enablement requirements are defined by 35 U.S.C. § 112, first paragraph, which states that the patent specification must contain "a written description of the invention, and of the manner and process of making and using it…[such] as to enable any person of ordinary skill in the art to which it pertains … to make and use the same … " The purpose of the written description requirement is to prevent a patentee from later asserting that

he invented something which he did not. Thus the patentee must "recount his invention in such detail that his future claims can be determined to be encompassed within his original creation." *Vas- Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1561, 19 U.S.P.Q.2d 1111, 1115 (Fed. Cit 1991).

b. Analysis

It is believed the rejection is in error. The specification clearly supports the use of a steroidal anti-inflammatory that is of greater potency than 1 wt% hydrocortisone, which is explicitly stated to be of little if any benefit. This can be found at page 5, lines 13-15.

There is no requirement for the exact language to be provided in the specification. The written requirement, as discussed above, is met if the description conveys to one of skill in the art that which is defined by the claim.

(ii) Rejections Under 35 U.S.C. § 102

Claims 1-10 and 13-17 were rejected under 35 U.S.C. § 102(a) as disclosed by U. S. Patent No. 6,444,647 to Robinson *et al.* ("Robinson"). Claims 1-5, 7-13 and 17 were rejected under 35 U.S.C. § 102(b) as disclosed by U. S. Patent No. 6,075,056 to Quigley *et al.* ("Quigley"). Claims 1-9, 13, 14, 16 and 17 were rejected under 35 U.S.C. 102(b) as disclosed by U. S. Patent No. 5,686,089 to Mitra *et al.* ("Mitra"). Claims 1-10 and 17 were rejected under 35 U.S.C. § 102(b) as disclosed by U. S. Patent No. 5,219,877 to Shah *et al.* ("Shah").

a. The Legal Standard for Novelty under 35 U.S.C. 102.

For a rejection of claims to be properly founded under 35 USC §102, it must be established that a prior art reference discloses each and every element of the claims. *Hybritech Inc v*

Monoclonal Antibodies Inc, 231 USPQ 81 (Fed. Cir. 1986), *cert. denied*, 480 US 947 (1987); *Scripps Clinic & Research Found v Genentech Inc*, 18 USPQ2d 1001 (Fed. Cir. 1991). The Federal Circuit held in *Scripps*, 18 USPQ2d at 1010:

> Invalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference. . . *There must be no difference* between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention. (Emphasis added)

A reference that fails to disclose even one limitation will not be found to anticipate, even if the missing limitation could be discoverable through further experimentation. As the Federal Circuit held in *Scripps, Id.*:

> [A] finding of anticipation requires that all aspects of the claimed invention were already described in a single reference: a finding that is not supportable if it is necessary to prove facts beyond those disclosed in the reference in order to meet the claim limitations. The role of extrinsic evidence is to educate the decision-maker to what the reference meant to persons of ordinary skill in the field of the invention, not to fill in the gaps in the reference.

In the present case, the examiner has adopted the position that, having the answer in hand, that of selecting a narrow class of low to low-medium potency steroidal anti-inflammatory compounds, and combining this with an antifungal, the prior art discloses the claimed subject matter through its disclosure of ***all*** of the steroidal anti-inflammatory compounds in combination

with an antifungal. The courts have held, however, that the disclosure of a broad genus does not disclose a narrow selection, where that narrow selection has properties that could not be predicted from the properties as a whole. The prior art, as discussed in more detail below, does not disclose selecting the claimed class of steroidal anti-inflammatory in combination with an antifungal. The proper rejection in a situation such as this was to make an obviousness rejection over the prior art, arguing that one of ordinary skill in the art could pick and choose among a variety of prior art references to identify examples of the claimed class of anti-inflammatories and know to combine them with antifungals.

This analysis is discussed in detail by the Court of Appeals for the Federal Circuit and its predecessor the Court of Claims and Patent Appeals, further noting that this obviousness rejection may be overcome by a showing (see Dr. Goldstein's declaration, discussed below) that the range (or selection, as in this case) is critical.

> "In general, an appellant may overcome a *prima facie* case of obviousness by establishing 'that the [claimed] **range** is critical, generally by showing that the claimed **range** achieves unexpected results relative to the prior art **range.**' In re Geisler, 116 F.3d at 1469-70, 43 USPQ2d at 1365 (alteration in original) (quoting In re Woodruff, 919 F.2d at 1578, 16 USPQ2d at 1936)."A "showing of **unexpected results** must be commensurate in scope with the claimed range. See In re Greenfield, 571 F.2d 1185, 1189, 197 USPQ 227, 230 (CCPA 1978)

The fact that a claimed compound may be encompassed by a disclosed generic formula does not by itself render that compound obvious. In re Jones, 958 F.2d 347, 350, 21 U.S.P.Q.2D (BNA) 1941, 1943 (Fed. Cir. 1992) (rejecting Commissioner's argument that "regardless how broad, a disclosure of a chemical genus renders obvious any species that happens to fall within it"). "[A] reference must be considered not only for what it expressly teaches, but also for what it fairly suggests." In re Burckel, 592 F.2d 1175, 1179, 201 U.S.P.Q. (BNA) 67, 70 (CCPA 1979).

Rejections under 35 USC 102 are proper only when the claimed subject matter is identically disclosed or described in "the prior art." Thus, for the instant rejection under 35 USC 102(e) to have been proper, the Flynn reference must clearly and unequivocally disclose the claimed compound or direct those skilled in the art to the compound without any need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited reference. Such picking and choosing may be entirely proper in the making of a 103, obviousness rejection, where the appellant must be afforded an opportunity to rebut with objective evidence any inference of obviousness which may arise from the similarity of the subject matter which he claims to the prior art, but it has no place in the making of a 102, anticipation rejection. In re Arkley, et al., 59 C.C.P.A. 804; 455 F.2d 586; 172 U.S.P.Q. (BNA) 524 (CCPA 1972).

b. The Legal Standard to Rebut Obviousness under 35 U.S.C. 103

As discussed above, the invention is the selection of the class of low to low-mid potency steroidal anti-inflammatories that can be used in combination with antifungal medication to treat a patient with efficacy but with minimal side effects.

The examiner has pointed to several references in the cited art where it is noted that ultra-high and high potency halogenated or fluorinated anti-inflammatory steroids cause serious side effects, and asserted that this is a teaching towards the claimed selection (despite being irrelevant to a novelty analysis). However, the claims are not drawn solely to low to mid-potency anti-inflammatory steroids but to the combination of the anti-inflammatories with anti-fungal compounds. The claimed formulations have two functions, one of which is to treat a fungal infection and the other of which is to diminish inflammation. The two act by different mechanisms, which may in fact work against each other. It is well known that by decreasing inflammation, one also decreases the anti-infective capabilities of the body. The data presented by Dr. Goldstein establishes that the claimed compositions are both safe and efficacious. No where has the examiner pointed to where one of ordinary skill in the art would expect the combination of this ***selection*** to be safe and efficacious, as opposed to a combination of a low potency hydrocortisone and antifungal or a high potency anti-inflammatory and antifungal. Indeed, the only disclosure in the prior art cited by the examiner refers to selection of the anti-inflammatory; not to the selection of the antifungal so that the two are together safe and efficacious.

It is important to note that the prior art did not recognize that the selection of ***both*** the anti-inflammatory and the antifungal are required for efficacy.

As Dr. Goldstein's declaration establishes, many of the patients had previously been treated with strong anti-inflammatories. Counter-intuitively, the stronger anti-inflammatory creates more inflammation, not less, and thinning of the skin. The data originally presented at the interview demonstrates the unexpected efficacy and lack of side effects of one non-halogenated steroidal antiinflammatory, desonide, in combination with an antifungal. Additional data showing the same unexpected efficacy and lack of side effects for other members of the claimed class of low to low-mid potency steroidal antiinflammatories was submitted in the Declaration under 37 C.F.R. § 1.132 by Dr. Goldstein. Members of the claimed class that have been shown to produce results comparable to a topical cream containing 0.05% desonide and 1% clotrimazole are:

Clotrimazole 1% cream with alclometasone dipropionate 0.05% cream applied twice daily;

Oxicanozole cream 1% with Hydrocortisone cream 2½% applied twice daily;

Econazole cream 1% with fluocinalone acetonide cream 0.01% applied twice daily; and

This data is comparative data, since the patients were initially treated with high potency steroidal anti-inflammatories in combination with antifungal agents. The unexpected efficacy of the small class of claimed low and mid-potency steroidal anti-inflammatories in combination with an antifungal could not have been predicted in view of the prior art, discussed in more detail

below, which, to the extent it provides any teaching other than a "grocery list of compounds", teaches away from using weaker anti-inflammatories.

In re Soni, 54 F.3d 746, 34 USPQ2d 1684 (Fed. Cir. 1995) makes clear that such evidence must be considered in evaluating the obviousness of a claimed invention. **"In arriving at its judgment regarding whether the claimed invention would have been obvious, the trial court should have given appropriate weight to the evidence of unexpected results"**. See also Stratoflex, 713 F.2d at 1538, 218 U.S.P.Q. (BNA) at 879 ("It is jurisprudentially inappropriate to disregard any relevant evidence on any issue in any case, patent cases included. Thus evidence arising out of the so-called 'secondary considerations' must always when present be considered en route to a determination of obviousness."); In re Soni, 54 F.3d at 750, 34 U.S.P.Q.2D (BNA) at 1687; In re Chu, 66 F.3d 292, 298, 36 U.S.P.Q.2D (BNA) 1089, 1094 (Fed. Cir. 1995); In re Oetiker, 977 F.2d 1443, 1445, 24 U.S.P.Q.2D (BNA) 1443, 1444 (Fed. Cir. 1992); In re Piasecki, 745 F.2d 1468, 1471-72, 223 U.S.P.Q. (BNA) 785, 787 (Fed. Cir. 1984) ("All evidence on the question of obviousness must be considered, both that supporting and that rebutting the prima facie case.")

c. Detailed Analysis of the Prior Art

Quigley

U.S. Patent No. 6,075,056 to Quigley *et al.* discloses the use of steroidal antiinflammatories with a wide range of potencies (*see* col. 2, lines 7-10; col 4, line 55 to col. 5, line 51). There is no recognition that the potency of the steroidal antiinflammatory is the cause

of the side effects and can be eliminated not by changing the carrier as suggested by Quigley but by selecting a narrow class of steroidal antiinflammatories.

Shah

U.S. Patent No. 5,219,877 to Shah *et al.* describes a gel formulation for topical administration including an imidazole antifungal in combination with a mid-potency steroidal antiinflammatory. As described at col. 4, lines 3-16, this class of compounds is not within the claimed class of low and low-mid potency steroidal antiinflammatories.

Mitra

U.S. Patent No. 5,686,089 to Mitra et al. describes treatment with a topical formulation to treat infections with an antimicrobial agent (col. 3, lines 1-49) which can include an antiinflammatory (col. 6, line 65 to col. 7, line 28). There is no teaching of the claimed class of low and low-mid potency steroidal anti-inflammatories, the problems with treatment with mid and high potency antiinflammatories, nor that one should select low or low-mid potency steroidal antiinflammatories.

Robinson

U.S. patent No. 6,444,647 to Robinson, et al. describes a skin care composition containing, as active ingredients, a vitamin B3 compound, farnesol, phytantriol or mixtures thereof, and a carrier. There is nothing teaching one to select low to low-mid potency steroidal antiinflammatories for treatment of skin conditions.

Summary

Claims 1-17

There is no teaching in the prior art that one should select low to low-mid potency steroidal anti-inflammatories in combination with anti-fungals to avoid side effects and have efficacy. Accordingly, all of claims 1-17, which require the selection of this combination, are novel.

Claims 4-6

None of the prior art teaches the specific combination of desonide and clotrimazole. Accordingly, claims 4-6 are novel.

Claims 11 and 12

None of the prior art teach the specific formulations of claims 11 and 12. Accordingly, claims 11 and 12 are novel.

Claims 14-16

None of the cited art teach applying the specific combination of claims 1-13 or 17 in a thin layer two times a day. Accordingly, claims 14-16 are novel.

(iv) Rejections Under 35 U.S.C. § 103

Claim 15 is non-obvious as required by 35 U.S.C. § 103 over U.S. Patent No. 5,686,089 to Mitra Claims 1-14, 16 and 17 are also non-obvious as required by 35 U.S.C. 103.

a. Legal Standard

References relied upon to support a rejection under 35 U.S.C. § 103 must provide an enabling disclosure, i.e., "they must place the claimed invention in the possession of the public." *Application of Payne*, 606 F.2d 303, 314, 203 U.S.P.Q. 245 (C.C.P.A. 1979); *see Beckman Instruments, Inc. v. LKB Produkter AB*, 892 F.2d 1547, 13 U.S.P.Q.2d 1301 (Fed. Cir. 1989). A publication that is insufficient as a matter of law to constitute an enabling reference may still be relied upon, but only for what it discloses. *See Reading & Bates Constr. Co. v. Baker Energy Resources Corp.*, 748 F.2d 645, 651-652, 223 U.S.P.Q. 1168 (Fed. Cir. 1984); *Symbol Technologies, Inc. v. Opticon, Inc.*, 935 F.2d 1569 (Fed. Cir. 1991).

"Focusing on the obviousness of substitutions and differences, instead of on the invention as a whole, is a legally improper way to simplify the often difficult determination of obviousness." *Gillette Co. v. S.C. Johnson & Sons, Inc.*, 919 F.2d 720, 724, 16 U.S.P.Q.2d 1923 (Fed. Cir. 1990); *see Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1383, 231 U.S.P.Q. 81, 93 (Fed. Cir. 1986). "One cannot use hindsight reconstruction to pick and choose among isolated disclosures on the prior art to deprecate the claimed invention." *In re Fine*, 837 F.2d 1071, 1075 (Fed. Cir. 1988).

The prior art must provide one of ordinary skill in the art with the motivation to make the proposed modifications needed to arrive at the claimed invention. *See In re Geiger* , 815 F.2d 686, 2 U.S.P.Q.2d 1276 (Fed. Cir. 1987); *In re Lalu and Foulletier*, 747 F.2d 703, 705, 223 U.S.P.Q. 1257, 1258 (Fed. Cir. 1984). Claims for an invention are not *prima facie* obvious if the primary references do not suggest all elements of the claimed invention and the prior art does not

suggest the modifications that would bring the primary references into conformity with the application claims. *In re Fritch*, 23 U.S.P.Q.2d, 1780 (Fed. Cir. 1992). *In re Laskowski*, 871 F.2d 115 (Fed. Cir. 1989). This is not possible when the claimed invention achieves more than what any or all of the prior art references allegedly suggest, expressly or by reasonable implication.

Obviousness is determined as follows. "A proper analysis under § 103 requires, *inter alia*, consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process; and (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success." *Noelle v. Lederman*, 355 F.3d 1343, 69 USPQ2d 1508 (Fed. Cir. 2004) Both a suggestion to make a claimed composition or process and a reasonable expectation of success must be founded in the prior art, not in the appellant's disclosure. *Velander v. Garner*, 348 F.3d 1359, 68 USPQ2d 1769 (Fed. Cir. 2003); *see also In re Dow Chem. Co.*, 837 F.2d 469, 473 (Fed. Cir. 1988).

b. Analysis

The prior art is discuss above. The legal basis for making a rejection under 35 U.S.C. 103 is also discussed, as is the requirement that the examiner must take into consideration the evidence of non-obviousness. The prior art does not teach the selection of the class of low and low-mid potency steroidal anti-inflammatories in combination with an antifungal. The prior art does not recognize that the combination of a stronger steroidal-anti-inflammatory with an

antifungal is ineffective to treat the fungal disease, while causing side effects due to the strength of the steroidal anti-inflammatory. The evidence submitted by the appellant makes clear that surprisingly, and based on many years of evidence achieved only through trial and error and direct patient treatment and observation, could one determine that this specific class of compositions would be effective. This evidence covers a wide range of both the low and low-mid potency steroidal anti-inflammatories and antifungals. The examiner has provided no argument, nor indeed has he ever addressed, this evidence. Absent evidence to the contrary, deference must be given to the appellant. Accordingly, all of claims 1-17 are novel and non-obvious.

(8) SUMMARY AND CONCLUSION

In summary, appellant has demonstrated that the claimed combination unexpectedly provides efficacy and safety, which is neither disclosed by, nor recognized or suggested in the prior art. Allowance of all claims 1-17 is earnestly solicited.

Respectfully submitted,

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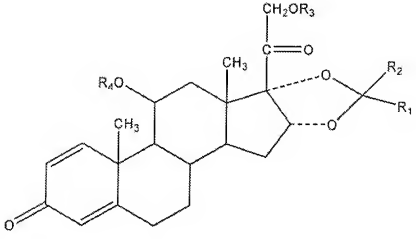
APPENDIX: CLAIMS

1. (previously presented) A topical antifungal composition comprising:

a) a therapeutically effective amount of an antifungal compound for treating a fungal disease or a pharmaceutically acceptable salt thereof; and

b) a therapeutically effective amount of a low to low-medium potency steroidal anti-inflammatory causing minimal skin atrophy, striae and hypopigmentation, in a concentration between 0.01 wt% and 5.0 wt%, and having a higher potency than 1 wt% hydrocortisone.

2. (previously presented) The antifungal composition of claim 1 wherein the steroidal anti-inflammatory has the following structure:



wherein R_1, R_2, R_3, and R_4 taken independently can be H, C1-C10 alkyl, C1-C10 alkenyl, C3-C10 cycloalkyl, and phenyl groups; R_1 and R_2 taken together can be C3-C10 cycloalkyl; and R_3 and R_4 taken independently can be H, C1-C10 alkyl, C1-C10 alkenyl, C3-C10 cycloalkyl, phenyl, C7-C10 phenylalkyl, carboxylate, sulfonyl, phosphoryl, and phosphonyl groups.

3. (previously presented) The composition of claim 1 wherein R_1, R_2, R_3, and R_4 groups are independently H, CH_3, ethyl, propyl, phenyl, and phenylmethyl groups.

4. (previously presented) The composition of claim 2 wherein the steroidal anti-inflammatory is desonide and the antifungal compound is clotrimazole.

5. (original) The composition of claim 4 containing 0.01 wt % to 5.0% wt % desonide.

6. (original) The composition of claim 5 containing 0.1 wt % to 5 wt % clotrimazole.

7. (previously presented) The composition of claim 1 wherein the steroidal anti-inflammatory is selected from the group consisting of Fluocinolone acetonide, Hydrocortisone valerate, Hydrocortisone butyrate, Alclometasone dipropionate, Desonide, and hydrocortisone probutate.

8. (original) The composition of claim 1 wherein the antifungal is selected from the group consisting of polyene type antifungal agents and azole type antifungal agents.

9. (original) The composition of claim 8 wherein the antifungal is selected from the group consisting of Amphoterican B, Nystatin, Flucytosin, Natamycin, Ketoconazole, Econoazole, Miconazole, Itraconazole, Fluconazole, Econazole, Clotrimazole, Griseofulvin, Oxiconazole. Terconazole, Tioconazole, Clotrimazole, Silver Sulfadiazine, Ciclopirox olamine, and Terbinafine.

10. (original) The composition of claim 1, wherein the composition is formulated as a cream, ointment, gel, lotion, foam, powder, aerosol, spray, shampoo, or liquid solution.

11. (original) The composition of claim 10 having a pH of about 3.5 to about 7.0 further comprising: at least one solvent, at least one emollient, at least one humectant, at least one preservative, and at least one emulsifier; and optionally including an acid, base, or buffering agent to adjust the pH.

12. (original) The composition of claim 11, wherein the solvent is selected from the group consisting of propylene glycol, butylene glycol, hexylene glycol, polyethylene glycols, polypropylene glycols, and polyurethane compounds; the emollient is selected from the group consisting of white petrolatum, mineral oil, propylene glycol dicaprylate, lower fatty acid esters and lower alkyl ethers of propylene glycol, cetyl alcohol, cetostearyl alcohol, stearyl alcohol, stearic acid, cetyl esters wax, spermaceti wax, and white wax; the humectant is selected from the group consisting of glycerin and sorbitol; and the emulsifier is selected from the group consisting of glyceryl monostearate, glyceryl monoleate, stearic acid, polyoxyethylene cetyl ether, polyoxyethylene cetostearyl ether, polyoxyethylene stearyl ether, and polyethylene glycol stearate; wherein the optional acid is selected from the group consisting of hydrochloric acid and phosphoric acid, the optional base is chosen from diethanolamine, triethanolamine, and sodium hydroxide, the optional buffering agent is chosen from monobasic sodium phosphate and dibasic sodium phosphate, and the preservative is chosen from benzyl alcohol, sodium benzoate and parabens.

13. (original) The composition of claim 1 wherein the antifungal is in an amount effective to treat fungal disease selected from the group consisting of tinea pedis, tinea capitis, tinea corporis, tinea versicolor, scalp disorders, tinea cruris, and candidiasis.

14. (previously presented) A method of treating a fungal disease comprising administering to a subject in need of treatment the composition of any of claim 1-13 or 17, with a thin application of the composition two times per day to the affected areas.

15. (original) The method of claim 14 wherein the subject is a child of under 10 years old.

16. (original) The method of claim 14 wherein the fungal disease is selected from the group consisting of tinea pedis, tinea capitis, tinea corporis, tinea versicolor, scalp disorders, tinea cruris, and candidiasis.

17. (previously presented) The composition of claim 1 wherein the steroidal antiinflammatory is not halogenated.

APPENDIX: EVIDENCE

Declaration under 37 C.F.R. § 1.132 by Dr. Goldstein

National Psoriasis – Potencies of Topical Steroids

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Jay A. Goldstein, Michael Rothman, and Whe-Yong Lo		
Serial No.:	10/691,928	Art Unit:	1616
Filed:	October 23, 2003	Examiner:	David Paul Stitzel
For:	*ANTIFUNGAL FORMULATIONS*		

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 C.F.R. § 1.132

Sir:

I, Jay A. Goldstein, hereby declare that:

1. I am a co-inventor of the above-identified application. I have been a licensed physician since July 1973. I began my medical career as an Emergency Physician, and practiced this specialty for four years. In September of 1977, I started training in Dermatology, and became a fully trained Board Certified Dermatologist in November of 1980. My CV is attached.

2. During my long medical career, both as an Emergency Physician, and as a Dermatologist, I have found that rashes, and particularly inflammatory tinea (ringworm) were a particularly common and often stubborn problem to treat. Such rashes respond to topical anti-fungals, but in a very slow fashion. It can take up to 4-6 weeks for these rashes to clear and for the patient to be symptom free. Even as the rash fades, the patient is still often bothered by intense, unremitting itching, burning and discomfort. There was, and is a product, Lotrisone,

which was developed to both treat the tinea, as well as the accompanying inflammation and itching, which were often the main reasons that the patient sought medical attention. Lotrisone was a combination of anti-fungal clotrimazole with a high potency corticosteroid, betamethasone dipropionate. This drug was effective in clearing the tinea, as well as rapidly decreasing the itching, which without the steroid, would normally last up to several weeks. With Lotrisone, however, the itching component would often disappear within days, making the patient more comfortable. The problem with Lotrisone, however, was that the steroid was too potent to be used safely on thin skinned area of the body, and thus often caused stretch marks, thinning of the skin, as well as other changes.

3. Because of my many years of experience both as an Emergency Room Physician, and as a Dermatologist, I saw the need for a preparation which would address both the fungal infection, as well as the intense itching and inflammation associated with the fungal infection. While others thought that perhaps slightly lower potency or even higher potency steroids would be acceptable, I felt that any steroid other than those safe for use on the face and other thin skinned area would not be appropriate. Of course, there was the risk that lower potency steroids would not be effective. I began using anti-fungal preparations in conjunction with low potency topical steroids on my patients with inflammatory tinea, and found that in fact such preparations were both safe and effective. They shortened the time to clearing of the fungus, and they dramatically decreased the symptoms of redness and especially itching. It would have been unethical to compare the type of products that I used with compounds using stronger, more potent steroids, as there would be the real risk of major untoward side effects.

4. I have developed a formulation that rapidly clears both their fungus, and their associated symptoms of itching and inflammation. This is further demonstrated by studies conducted using topical compositions containing a combination of an antifungal agent in combination with a low to mid potency anti-inflammatory steroid in the treatment of fungal diseases and their related inflammation, especially for conditions such as tinea cruris, intertriginous dermatitis, and tinea corporis.

5. Case Report

Patient: C.S, 74 y.o. White male

History of Present Illness: Long standing recurrent tinea cruris of inguinal folds.

Initial Treatment: None

Physical Examination: Erythema with scale in inguinal folds.

Diagnosis: Tinea Cruris

Treatment: Clotrimazole 1% cream with alclometasone dipropionate 0.05% cream applied twice daily.

Results: Complete clearing after several weeks of usage.

6. Case Report

Patient: B.T. 72 y.o. White female

History of Present Illness: Several days of pruritic inflamed eruption beneath right breast.

Prior Treatment: None

Physical Examination: Erythematous dermatitis beneath right breast.

Diagnosis: Intertriginous Dermatitis.

Treatment: Oxiconazole cream 1% with Hydrocortisone cream 2½% applied twice daily.

Results: Marked clearing at seven days.

7. Case Report

Patient: D.E. 52 y.o. White male.

History of Present Illness: Two months of very pruritic eruption beginning on left foot, spreading to right hand.

Initial Treatment: None

Physical Examination: Well-defined, annular, scaly, erythematous, inflamed eruption on dorsum surface left foot, with similar plaque on right hand.

Diagnosis: Tinea Corporis

Treatment: Econazole cream 1% with fluocinalone acetonide cream 0.01% applied twice daily.

Results: Marked decrease of pruritus within 3 days. Eruption essentially cleared at 3 weeks.

8. Case Report

Patient: M.B. 61 y.o. White male

History of Present Illness: Eruption of lower legs of several months duration. Known history of "tinea."

Prior Treatment: None

Physical Examination: Plaques of annular dermatitis of lower legs, right greater than left. 10 toenail onychomycosis.

Diagnosis: Tinea corporis, with tinea pedis and onychomycosis.

Treatment: Econazole cream 1% with alclometasone dipropionate 0.05%, applied twice daily.

Results: Marked clearing at 3 weeks, but with some residual eczematous changes still present.

9. Case Report

Patient: R.B. 62-year old white male.

History of Present Illness. Eruption began on right lower leg in mid-August. No response to topical steroids.

Physical Examination: Raised annular eruption on right lower leg.

Laboratory. Biopsy on September 26, 2005 revealed hypersensitivity reaction.

Additional Treatment. High potency steroids again prescribed without effect.

Additional laboratory Test. Special stains revealed inflammatory tinea.

Treatment: Application twice daily of desonide cream and clotrimazole cream together resulted in essentially complete clearing within two weeks.

10. In summary, oxiconazole cream 1% with hydrocortisone cream 2½% applied twice daily and econazole cream 1% with fluocinalone acetonide cream 0.01% applied twice daily resulted in marked clearing of pruritus and the eruption at 3 weeks. Clotrimazole 1% cream with acalmetasone dipropionate 0.05% cream applied twice daily was effective in completely clearing long standing recurrent tinea cruris, after several weeks of usage. Econazole cream 1% with alclometasone dipropionate 0.05% applied twice daily resulted in marked clearing of eruption in a patient with a history of tinea.

11. The compositions used in the examples above have advantages over other compositions which contain very potent steroids such as betamethasone and dexamethasone

(see Goodman and Gilman's The Pharmacological Basis of Therapeutics, 9th edition, 1996, p1466, attached) associated with severe side effects. It is undesirable to use mid-potency or higher potency steroids for topical treatment for extended periods of time because of associated risks. The compositions exemplified above employ low potency, Class 6 steroids (see attached potency chart of steroids listed by the National Psoriasis Foundation), i.e. fluocinalone acetonide, alclometasone dipropionate, desonide, and hydrocortisone 2 ½%. Other commercialized products have utilized only 1% hydrocortisone, which is too low in potency to have significant anti-inflammatory properties. We utilize prescription strength steroids that are safe for all parts of the skin, are safe for extended periods of use, but have superior potency as compared to OTC products.

12. I declare that all statements made herein of my own knowledge and belief are true and that all statements made on information and belief are believed to be true, and further, that the statements are made with the knowledge that willful false statements are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: 12/21/10

Jay A. Goldstein

Curriculum Vitae

Identifying Information	Jay A. Goldstein, M.D. 31 Claremont Street Newton, Massachusetts 02158
Office Address	67 Union Street – Suite 501 Natick, Massachusetts 01760
Date and Place of Birth	January 9, 1947 Paterson, New Jersey
Citizenship	U.S.A.
Pre-medical Education	Boston University School of Medicine 1968 – 1972 M.D., 1972
Internship	Herrick Memorial Hospital Berkeley, California 1972 –1973 Rotating
Residency	Boston University Medical Center Dermatology 1977 – 1980
Licensure	Massachusetts #39484 Rhode Island #9865
Certification	American Board of Dermatology, 1980
Professional Societies	American Academy of Dermatology Society of Investigative Dermatology
Academic Appointments	Boston University School of Medicine, Associate in Dermatology
Hospital Appointments	Metrowest Medical Center Natick, Massachusetts Boston Medical Center Boston, Massachusetts
Publications	1. Goldstein JA and Pochi PE: Failure of Benzoyl Peroxide to Decrease Sebaceous Gland Secretion in Acne Dermatologica 162: 287-291, 1981

Curriculum Vitae

2. Shalita AR, Strauss JS: Comparative Effect of Isotretinoin and Etretinate on Acne and Sebaceous Gland Secretion. Journal of the American Academy of Dermatology 6: 760-765, 1982

3. Goldstein JA, Comite H, Mescon H, Pochi PE: Isotretinoin in the Treatment of Acne: Histologic Changes, Sebum Production, and Clinical Observations. Archives of Dermatology 118: 555-562, 1980

4. Goldstein JA, Pochi PE: Adolescent Acne. The Female Patient 5: 57-66, 1980

5. Barza M, Goldstein J, Kane A, Feingold DS, Pochi, P: Systemic Absorption of Clindamycin Hydrochloride After Topical Application. Journal Amer Acad Dermatol 7: 208-14, 1982

Corticosteroids are grouped according to their relative potencies in Na^+ retention, effects on carbohydrate metabolism (*i.e.*, hepatic deposition of glycogen and gluconeogenesis), and antiinflammatory effects. In general, potencies of steroids as judged by their ability to sustain life in the adrenalectomized animal closely parallel those determined for Na^+ retention. Potencies based on effects on glucose metabolism closely parallel those for antiinflammatory effects. The effects on Na^+ retention and the carbohydrate/antiinflammatory actions are not closely related. Based on these differential potencies, the corticosteroids traditionally are divided into mineralocorticoids and glucocorticoids. Estimates of potencies of representative steroids in these actions are listed in Table 59–2. It should be kept in mind, however, that a number of steroids that are predominantly classified as glucocorticoids, such as cortisol and prednisone, also possess modest but significant mineralocorticoid activity. Clinically significant changes in fluid and electrolyte handling can result from the mineralocorticoid effects of these "glucocorticoids." In contrast, aldosterone is exceedingly potent with respect to Na^+ retention but has only modest potency for effects on carbohydrate metabolism. At normal rates of secretion by the adrenal cortex or in doses that maximally affect electrolyte balance, aldosterone has no significant glucocorticoid activity and thus acts as a pure mineralocorticoid.

General Mechanisms for Corticosteroid Effects. Corticosteroids interact with specific receptor proteins in target tissues to regulate the expression of corticosteroid-responsive genes, thereby changing the levels and array of proteins synthesized by the various target tissues (*see* Figure 59–5). As a consequence of the time required for changes in gene expression and protein synthesis, most effects of corticosteroids are not immediate, but become apparent after several hours. This fact is of clinical significance, because a delay generally is seen before beneficial effects of corticosteroid therapy become manifest. Although corticosteroids predominantly act to increase expression of target genes, there are well-documented examples where glucocorticoids decrease transcription of target genes, as discussed below. In contrast to these genomic effects, recent studies have raised the possibility that some actions of corticosteroids are immediate and are mediated by membrane-bound receptors (Wehling, 1994).

Through the use of molecular biologic approaches, the receptors for the corticosteroid hormones have been cloned and their structures determined. These receptors are members of a superfamily of structurally related proteins, the nuclear receptors, that transduce the effects of a diverse array of small, hydrophobic ligands, including the steroid hormones, thyroid hormone, vitamin D, and retinoids (Mangelsdorf *et al.*, 1994). These receptors share two highly conserved domains: a region of approximately 70 amino acids forming two zinc-binding domains, termed *zinc-fingers*, that are essential for the interaction of the receptor with specific DNA sequences, and a region at the carboxy terminus that interacts with ligand (the ligand-binding domain). Removal of the ligand-binding domain from the glucocorticoid receptor leads to its constitutive activation (*i.e.*, activation in the absence of ligand), suggesting that the glucocorticoids activate their receptor by relieving the inhibitory influence of the carboxy-terminal region.

Table 59–2
Relative Potencies and Equivalent Doses of Representative Corticosteroids

COMPOUND	ANTI-INFLAMMATORY POTENCY	Na^+-RETAINING POTENCY	DURATION OF ACTION*	EQUIVALENT DOSE†, mg
Cortisol	1	1	S	20
Cortisone	0.8	0.8	S	25
Fludrocortisone	10	125	S	‡
Prednisone	4	0.8	I	5
Prednisolone	4	0.8	I	5
6α-methylprednisolone	5	0.5	I	4
Triamcinolone	5	0	I	4
Betamethasone	25	0	L	0.75
Dexamethasone	25	0	L	0.75

* S, short (*i.e.*, 8–12 hour biological half-life); I, intermediate (*i.e.*, 12–36 hour biological half-life); L, long (*i.e.* 36–72 hour biological half-life).

† These dose relationships apply only to oral or intravenous administration, as glucocorticoid potencies may differ greatly following intramuscular or intraarticular administration.

‡ This agent is not used for glucocorticoid effects.

Topical steroids

Potencies of topical steroids

Topical steroid medications come in various strengths, ranging from very strong, or superpotent (
very weak, or least potent (Class 7). Once a person has stopped responding to a steroid of a par
strength or potency, it is unlikely he or she will respond to any brand of steroid at an equal or low
unless an extended period of time has elapsed. The potency chart below provides the potencies
of steroid medications used to treat psoriasis.

Generally, the stronger the steroid, the more effective it is in clearing psoriasis, but the risk of sid
also greater. The base, or formulation, of a steroid medication can also influence how much med
penetrates the tissue. Steroids come in a variety of bases, such as creams, ointments, gels, spra
solutions, lotions, foam and tape.

Potency chart

The following potency chart categorizes brand-name topical steroid medications along with the n
corresponding generic drug. The list positions these medications according to their potency. The
be comprehensive.

BRAND NAME	GENERIC NAME
CLASS 1 - Superpotent	
Clobex Lotion, 0.05%	Clobetasol propionate
Cormax Cream/Solution, 0.05%	Clobetasol propionate
Diprolene Gel/Ointment, 0.05%	Betamethasone dipropionate
Olux Foam, 0.05%	Clobetasol propionate
Psorcon Ointment, 0.05%	Diflorasone diacetate
Temovate Cream/Ointment/Solution, 0.05%	Clobetasol propionate
Ultravate Cream/Ointment, 0.05%	Halobetasol propionate
CLASS 2 - Potent	
Cyclocort Ointment, 0.1%	Amcinonide
Diprolene Cream AF, 0.05%	Betamethasone dipropionate
Diprosone Ointment, 0.05%	Betamethasone dipropionate
Elocon Ointment, 0.1%	Mometasone furoate
Florone Ointment, 0.05%	Diflorasone diacetate
Halog Ointment/Cream, 0.1%	Halcinonide

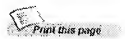
Lidex Cream/Gel/Ointment, 0.05%	Fluocinonide
Maxiflor Ointment, 0.05%	Diflorasone diacetate
Maxivate Ointment, 0.05%	Betamethasone dipropionate
Psorcon Cream 0.05%	Diflorasone diacetate
Topicort Cream/Ointment, 0.25%	Desoximetasone
Topicort Gel, 0.05%	Desoximetasone
CLASS 3 - Upper Mid-Strength	
Aristocort A Ointment, 0.1%	Triamcinolone acetonide
Cutivate Ointment, 0.005%	Fluticasone propionate
Cyclocort Cream/Lotion, 0.1%	Amcinonide
Diprosone Cream, 0.05%	Betamethasone dipropionate
Florone Cream, 0.05%	Diflorasone diacetate
Lidex-E Cream, 0.05%	Fluocinonide
Luxiq Foam, 0.12%	Betamethasone valerate
Maxiflor Cream, 0.05%	Diflorasone diacetate
Maxivate Cream/Lotion, 0.05%	Betamethasone dipropionate
Topicort Cream, 0.05%	Desoximetasone
Valisone Ointment, 0.1%	Betamethasone valerate
CLASS 4 - Mid-Strength	
Aristocort Cream, 0.1%	Triamcinolone acetonide
Cordran Ointment, 0.05%	Flurandrenolide
Derma-Smoothe/FS Oil, 0.01%	Fluocinolone acetonide
Elocon Cream, 0.1%	Mometasone furoate
Kenalog Cream/Ointment/Spray, 0.1%	Triamcinolone acetonide
Synalar Ointment, 0.025%	Fluocinolone acetonide
Uticort Gel, 0.025%	Betamethasone benzoate
Westcort Ointment, 0.2%	Hydrocortisone valerate
CLASS 5 - Lower Mid-Strength	
Cordran Cream/Lotion/Tape, 0.05%	Flurandrenolide
Cutivate Cream, 0.05%	Fluticasone propionate
DermAtop Cream, 0.1%	Prednicarbate
DesOwen Ointment, 0.05%	Desonide
Diprosone Lotion, 0.05%	Betamethasone dipropionate
Kenalog Lotion, 0.1%	Triamcinolone acetonide
Locoid Cream, 0.1%	Hydrocortisone butyrate

Pandel Cream 0.1%	Hydrocortisone probutate
Synalar Cream, 0.025%	Fluocinolone acetonide
Uticort Cream/Lotion, 0.025%	Betamethasone benzoate
Valisone Cream/Ointment, 0.1%	Betamethasone valerate
Westcort Cream, 0.2%	Hydrocortisone valerate
CLASS 6 - Mild	
Aclovate Cream/Ointment, 0.05%	Alclometasone dipropionate
DesOwen Cream, 0.05%	Desonide
Synalar Cream/Solution, 0.01%	Fluocinolone acetonide
Tridesilon Cream, 0.05%	Desonide
Valisone Lotion, 0.1%	Betamethasone valerate
CLASS 7 - Least Potent	
Topicals with hydrocortisone, dexamethasone, methylprednisolone and prednisolone	

Updated July 2004

Related links

- Topical steroids
- Internal use of steroids
- Methods of using topical steroids
- Side effects of topical steroids
- Tips for using topical steroids



APPENDIX: RELATED PROCEEDINGS

There are no related proceedings.